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Evaluation of Radiation Exposure from Diagnostic Radiology Examinations

Technique/Exposure Guides for the Craniocaudal Projection in Mammography

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How can you tell if the exposure levels used to produce radiographs in your facility are appropriate? The Food and Drug Administration's Center for Devices and Radiological Health (CDRH) recommends a three-step approach that staffs of radiology facilities can use to evaluate the appropriateness of the radiation levels used to produce diagnostic images (1,2). The three steps of the approach are for the staff of a facility to:

(1) become aware of exposure levels given to a defined reference patient during common projections in their facility;

(2) compare these exposures to values "generally accepted" as providing diagnostic quality images without unnecessary radiation; and

(3) consider taking corrective actions if these exposure levels consistently fall outside of the generally accepted values. Possible corrective actions include improving quality assurance programs, providing additional personnel training, modifying techniques, or upgrading equipment.

CDRH refers to the "generally accepted" exposure values as technique/exposure (T/E) guides to emphasize the fact that the exposure values should be related to the techniques used during a given projection (with technique broadly defined to include image receptor type). CDRH also suggests (1-3) that:

(1) the T/E guides be expressed in terms of ranges of acceptable values, because problems may be indicated by too little exposure as well as too much;

(2) the T/E guides be expressed in terms of entrance skin exposure free in air because this quantity is the most convenient for measurement and comparison; and

(3) the facility's exposure levels should be measured in a manner that allows valid comparison with the T/E guides (i.e., they should be measured under comparable conditions or should be converted to values expected under comparable conditions).

This publication presents CDRH suggestions for appropriate T/E guides for use with the mammographic craniocaudal projection. This type of projection is the most commonly used mammographic view and much exposure data is available for it. Even if a facility commonly uses another projection in mammography, problems affecting radiation exposure and image quality with one projection often are problems affecting all projections conducted with a particular x-ray imaging system. The use of T/E guides to detect and correct the problems with the craniocaudal projection will have a beneficial effect as well on exposure levels and image quality of other projections conducted on the same system.

Source of the Mammographic T/E Guides

CDRH originally developed the T/E guides for the Breast Exposure: Nationwide Trends (BENT) program (4). BENT, a combined Federal-State program, originated when studies showed that skin exposure levels from craniocaudal mammographic projections ranged from 0.25 R to 47 R depending upon the facility (5). Cards containing thermoluminescent dosimeters (TLD's) were mailed to mammography facilities and facility staffs were asked to expose them using their normal techniques for a standard craniocaudal view of a medium-density medium-size breast (approximately 6 cm compressed). The facility staffs returned the cards, along with information on the technique, for reading. CDRH then compared the exposure and technique information to criteria developed from manufacturers' recommendations, data from the Centers for Radiological Physics (6), information from the literature and from radiologists, and the experiences of State surveyors. Finally, radiation control personnel visited facilities whose exposure levels appeared to be unusually high or low or whose techniques appeared atypical and assisted the facilities in achieving increased production of diagnostically acceptable radiographs within the recommended exposure values.

BENT helped facility staffs to detect and correct exposure and/or technique problems. For this reason, CDRH encourages the individual mammography facility staffs to carry out their own evaluations using the exposure and technique ranges developed in the BENT program as T/E guides. Staffs that detect problems through these evaluations should correct those problems by using the services of manufacturers' representatives, physics consultants, or the facility personnel themselves.

Mammographic Craniocaudal T/E Guides

Staffs of facilities can use the following exposure at skin entrance values developed for BENT as criteria for determining if the radiation levels they are using during mammographic craniocaudal projections cause unnecessary radiation exposure and/or less than desirable image quality. The suggested ranges of acceptable exposures are related to the listed image receptors. Facilities that use other image receptors, such as the new (1983) Kodak Ortho M™ or DuPont MRF-31™ film, which should permit significantly lower exposures than even the rare earth film/screen systems listed below, will need to modify these ranges for use with their units. In addition, facilities using recently developed mammography grids will also need to modify these ranges because patient exposures will tend to be higher than with those systems using the same films and screens without grids.

Image receptor	Anode material	Entrance Skin Exposure (R)	Half value Layer (mm of Al)	Tube potential (kVp)
Conventional film/screen combination*	W	0.15 to 0.90	0.3 to 1.0	26 to 34
	Mo, W/Mo	0.30 to 1.80.	0.3 to 1.0	26 to 34
Rare earth or very fast conventional film/screen combinations*	W	0.10 to 0.60	0.3 to 1.0	26 to 34
	Mo, W/Mo	0.20 to 1.20	0.3 to 1.0	26 to 34
Xeroradiography**	W, W/Mo***	0.40 to 1.50	0.8 to 3.0	35 to 50
	Mo***	1.00 to 2.50	0.8 to 3.0	35 to 50

* Conventional film/screen combinations refer to calcium tungstate systems designed specifically for mammographic applications, such as DuPont Lo-Dose™. The second category refers to both rare-earth systems and the faster conventional systems which are intended specifically for mammographic applications, such as Kodak Min-R™ or DuPont Lo-Dose 2™. It should also be noted that the American College of Radiology has stated that only "an x-ray unit specialized for mammography" should be used with film screen systems (7).

** These figures are for units operated in the positive mode. Units operated in the negative mode require approximately 30 percent less exposure at skin entrance.

*** The American College of Radiology has stated that xeromammography should be performed with tungsten target tubes only (7).

Note that the values are for examinations of a medium-density and medium-size (6 cm compressed) breast. The entrance skin exposure values can be converted to midline dose values (**8**). [The National Council on Radiation Protection and the National Cancer Institute have stated that with proper care, midplane dose can be kept below 1.0 rad for two exposures (NCRP) or "per complete examination" (NCI) (**9,10**). No minimum dose for adequate quality was suggested by these groups.]

As noted in the footnotes to the table, groups have recommended against using some of the alternatives listed. It should be stressed then that the provision of T/E guides for a particular set of techniques should not be taken as necessarily implying FDA endorsement of the use of that set of techniques. The prime purpose of the T/E guides is not technique selection, but to provide information on appropriate exposure levels after the facility staff has selected the techniques in accordance with imaging needs.

Measurement Procedures

The facility staff must obtain measurements of the exposure levels they commonly use during mammographic craniocaudal projections for comparison with the T/E guides. Measurement procedures are discussed in more detail in another CDRH publication (11) but some general comments can be made. Exposure measurement devices fall into two general groups.

(1) Ionization chamber instruments are considered to provide the most accurate results. MDH x-ray monitors with 6 cm^3 ionization chambers were used in the BENT program, but other instruments may be used if they have a satisfactory energy response. With some x-ray monitors, specially-designed ion chambers with thin windows may need to be used. In all cases, the ion chamber must be properly calibrated at the low energy ranges used in mammography and the appropriate corrections applied to exposure data. Some provision must be made for centering the probe 6 cm above the table top while simultaneously minimizing the amount of scattering material near the probe.

(2) Surveyors may also use thermoluminescent dosimeters (TLD's) if the surveyors take proper precautions. In the BENT program, CDRH placed TLD's in a specially-designed dosimetry card that facility staffs were to position in the center of the mammography unit's x-ray beam (12). A cardboard spacer positioned the TLD's 6 cm above the tabletop. The dosimetry card included 3 mm of aluminum to ensure uniform backscatter conditions. CDRH then applied appropriate calibration factors to the data to yield free-in-air exposure levels. Because of these measurement conditions, exposures measured with TLD's placed directly on the patient are not directly comparable to the values on the table. Again it is essential that the TLD's be calibrated at the low energies used in mammography examinations and under conditions equivalent to those used in the measurements.

Both classes of exposure measuring devices require some financial investment. However, facility staffs may use this equipment, especially the ionization chambers, for other personnel monitoring, quality assurance evaluation and acceptance testing purposes on mammography units and, assuming that their energy response range is broad enough, on other units as well.

If the facility does not wish to purchase its own equipment, outside assistance may be available. The facility may already be using the services of physics consultants or manufacturer's representatives for calibration or quality assurance purposes, and little extra effort or cost is required to include mammography exposure evaluation during their visits. Various commercial sources also offer TLD monitoring assistance.

The facility staff also may wish to investigate the services that State or local radiation control agencies can provide. Such agencies routinely visit radiology facilities to determine if equipment complies with regulations, and may be able to conduct exposure evaluations for use with the T/E guides as part of these visits or during other visits. This may be particularly true of the more than 40 States that have had experience with the BENT program.

The following basic concepts should be considered when selecting a means of exposure evaluation.

(1) The energy response of the exposure measurement device must match the kVp range used in the facility. This is especially crucial for special purpose mammography units that produce lower energy radiation than other units.

(2) Facility staff should measure exposure levels for comparison with the T/E guides when the facility: (1) begins an exposure evaluation program; (2) installs new equipment (including image receptors); (3) makes major modifications in old equipment or in exposure and/or processing technique; or (4) notices problems suddenly appearing that might be due to a change in the exposure levels of the unit. Staffs also should take exposure measurements routinely between such major events. However, the facility can adjust the schedule for these measurements to meet its own needs on a cost effective basis. For example, a facility might initially measure exposure levels monthly but if the exposure levels remain stable, the measurement intervals could be increased. On the other hand, if the latest measurement reveals an abrupt change in exposure level, the frequency of monitoring may need to be increased to track the impact of corrective measures until the staff is confident that the problem has been solved.

(3) Finally, if the measured exposure for the technique and image receptor used in the facility falls outside the T/E guide, the facility's staff or its consultants should determine the reason for this and decide whether the exposure level can be brought within the T/E guide without sacrificing diagnostic quality. Only if necessary corrective actions are taken will the measurement and evaluation effort have been worthwhile.

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